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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,008	07/31/2003	Robert E. Richard	02-263	9358
27774	7590	02/13/2007	EXAMINER	
MAYER & WILLIAMS PC			KENNEDY, SHARON E	
251 NORTH AVENUE WEST				
2ND FLOOR			ART UNIT	PAPER NUMBER
WESTFIELD, NJ 07090			1615	
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE		DELIVERY MODE	
3 MONTHS	02/13/2007		PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/632,008	RICHARD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sharon E. Kennedy	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 13 November 2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-27 is/are pending in the application.  
 4a) Of the above claim(s) 24-27 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-23 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date: _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>03/04/2005; 01/20/2004</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action or the MPEP.

### ***Election/Restrictions***

Applicant's election with traverse of Group I in the reply filed on November 13, 2006 is acknowledged. The traversal is on the ground(s) that there is no burden to the examiner. This is not found persuasive because applicant's response is conclusory and does not point out why there is no burden. The examiner maintains that there is significant burden as set forth in the restriction requirement in the last office action.

The requirement is still deemed proper and is therefore made FINAL.

Claims 24-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on November 13, 2006.

### ***Claim Rejections - 35 USC § 102***

Claims 1, 2, 4, 5, 6, 7, 18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Picha, US 5,342,628. Picha discloses a drug diffusion polymer system for sustained release (abstract) comprising various polysiloxane polymers (column 4, lines 19-25) which may be used to form sustained release drug delivery systems or formulated as coatings on various medical instruments (column 1, line 57 to column 2,

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line 4 and column 5, lines 1-14). Regarding the specifically claimed polymers, one example of the polymeric matrix is a copolymer of dimethylpolysiloxane and polymethylmethacrylate. See column 4, lines 1-25, especially lines 23-25. See also line 17 disclosing polystyrene copolymers. Regarding the claimed "supplemental polymer", the Picha matrix expander meets this limitation.

Claims 8-17, 19, 21, 22, 23 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Picha '628. Regarding claim 8, applicant recites a very modest elongation at break for a medical device. Silicone polymers typically have very high elongation at break values. Accordingly, the examiner takes the position that in view the polymers claimed by applicant are identically described by Picha, the elongation at break is inherent from the disclosure. In the alternative, it would be obvious to one of ordinary skill in the art to modify the Picha polymer to have a higher elongation at break depending on the use of the Picha device. For example, it would be desirable to form an indwelling urinary catheter out of soft and flexible material.

Regarding the glass transition temperatures, these characteristics are inherent in the disclosed polymers. Silicone or siloxane polymers generally have a much lower glass transition temperature than any acrylic polymer. The claims do not recite anything other than what is generic.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Zaffaroni et al., US 3,896,819. Note that the wall of the delivery device may comprise siloxanes. See column 13, lines 13-39, especially line 29.

***Claim Rejections - 35 USC § 103***

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Picha '628. Applicant recites sterilizing the device with radiation. This is a common and preferred method of sterilization in the art. It would be obvious to one of ordinary skill in the art to sterilize the Picha devices in this manner to optimize patient safety.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Sharon E. Kennedy*  
Sharon E. Kennedy  
Primary Examiner  
Art Unit 1615